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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/587,116 05/02/00 QUAY

S 18072-000600

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TOWNSEND AND TOWNSEND AND CREW
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO CA 94111-3804

EXAMINER

PUNNALURI, P

ART UNIT

PAPER NUMBER

1627

DATE MAILED:

10/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/587,116

Applicant(s)

QUAY, STEVEN C.

Examiner

Padmashri Ponnaluri

Art Unit

1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-108 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-108 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s): ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Claims 1-108 are currently pending in this application.

Note: In an effort to enhance communication with our customers and reduce processing time, Group 1627 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Jyothsna Venkat, Supervisory Patent Examiner, at (703) 308-2439. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claim(s) 1-12 and 15-27, drawn to compounds, classified in class 549, subclass 321.
 - II. Claim(s) 13 and 14, drawn to a pharmaceutical formulation, classified in various classes/subclasses, for example, class 514, subclasses 449, 461, 471, 472 or 473.
 - III. Claim(s) 28-35, drawn to an immobilized compound, classified in various classes/subclasses, for example, class 436, subclasses 523-535.
 - IV. Claim(s) 36-38, drawn to a method for isolating a microbial receptor binding to a molecule, classified in various classes/subclasses, for example, class 435, subclass 243.
 - V. Claim(s) 39-51, drawn to an immunogenic conjugate, classified in various classes/subclasses, for example, class 424, subclasses 178.1, 179.1 or 180.1.
 - VI. Claim(s) 52, 57-60, drawn to an antibody and pharmaceutical composition, classified in various classes/subclasses, for example, class 424, subclasses 130+; class 530, subclasses 389.1+.
 - VII. Claim(s) 53-56, drawn to an isolated nucleic acid, an expression vector comprising the nucleic acid, a host cell, classified in class 536, subclass 23.1, or class 435, subclass 320.1.

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- VIII. Claim(s) 61, 64, 66, drawn to a method of treating or preventing a disease in a subject caused by microorganism by administering the antibody of claim 52, classified in various classes/subclasses, for example, class 530, subclass 389.1.
- IX. Claim(s) 62-63, 65, drawn to a method of treating or preventing a disease in a subject caused by a microorganism, by administering an immunogenic conjugate of claim 39 or vaccine of claim 51, classified in various classes/subclasses, for example, class 424, subclass 164.1.
- X. Claim(s) 67-70, drawn to a method of preventing or disrupting the formation of a biofilm, classified in various classes/subclasses, for example, class 424, subclass 164.1.
- XI. Claim(s) 71, 74-75, drawn to a method for controlling autoinducer responsive gene expression using the antibody of claim 52, classified in class 435, subclass 172.1+.
- XII. Claim(s) 72-73, drawn to a method for controlling autoinducer responsive gene expression using vaccine of claim 51 and immunogen of claim 39, classified in class 435, subclass 172.1+.
- XIII. Claim(s) 76-80, drawn to a library of compounds, classified in various classes/subclasses, for example, class 435, subclass 7.1 or DIG 34.
- XIV. Claim(s) 81-91, drawn to a method of detecting an autoinducer, classified in various classes/subclasses, for example, class 435, subclasses 7.1+.
- XV. Claim(s) 92-100, drawn to a method of monitoring the amount of autoinducer in a patient, classified in various classes/subclasses, for example, class 424, subclass 9.1.
- XVI. Claim(s) 101-104, drawn to method of isolating an autoinducer, classified in various classes/subclasses, for example, class 424, subclass 1.49.
- XVII. Claim(s) 105-108, drawn to a method of detecting an antibody and kit, classified in various classes/subclasses, for example, class 424, subclass 139.1.

2. The inventions are distinct, each from the other because of the following reasons:
3. Groups I, II, III, V, VI, VII and XIII represent separate and distinct products. They differ in respect to their properties, their use and the synthetic methodology for making them. Therefore, they have different issues regarding patentability and enablement and represent patentably distinct subject matter. This is elaborated upon below.
4. In the instant case, the compounds of Group I are different from all other groups as they represent single chemical entities of a specific structure. The pharmaceutical formulation of Group II, immobilized compound of Group III and immunogenic conjugate of Group VI all require that the compound of Group I, and have additional components or functions such as "biologically active agents" (Group II), "solid support" (Group III) or immunogenicity (Group V).
5. The antibody of group VI, and the nucleic acid, expression vector and host cell of Group VII are all completely different in structure than any of the products containing chemical compounds of a particular formula (i.e. Group I, II or III etc.).

6. Furthermore, the library of Group XIII is a composition comprising at least two members, while Group I represents distinct molecules. Libraries and compounds also have different uses and require different methods of making.

7. Groups I, II, III, V, VI, VII & XIII and groups IV, VIII-XII, XIV-XVII could be defined as related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the compounds of Group I can be used in a materially different process, such as starting materials for further lactone product syntheses; and the antibodies of group VI can be used in various methods of groups VIII, XI; and the use of the immunoconjugate or vaccine of group V with methods of groups IX, XII. Thus, restriction is proper.

8. Groups IV, VIII, IX, X, XI, XII, and XIV – XVII are different methods. The methods are different because they use different steps, require different reagents and will produce different products and/or results. They therefore have different issues regarding patentability and enablement and represent patentably distinct subject matter. This is elaborated upon below.

9. In the instant case, each of the methods requires different steps and produces a different result. That is, the method of Group IV isolates a microbial receptor; the method of Group VIII uses an antibody for treatment; the method of Group X prevents/disrupts a biofilm; the method

of Group XII controls gene expression; the method of Group XIV detects an autoinducer; the method of Group XV monitors the amount of autoinducer in a patient; the method of Group XII isolates an autoinducer and the method of Group XVII detects an antibody. Each one of these is a distinctly different end result that requires different steps to achieve and thus represents a different method.

10. Groups III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the immobilized compound of Group III can be used in a materially different process, such as for the creation of a library of solid supported compounds.

11. Note that the library of Group XIII is not disclosed as being used in any of the methods of Groups IV, VIII- XI, XIV- XVIII and thus is not related to any of these methods.

12. These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. Each of the different methods and products would require completely different searches in the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

13. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

15. Applicant is also reminded that a 1 - month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 703-305-3884. The examiner can normally be reached on alternative Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat can be reached on 703-308-2439. The fax phone

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numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

Padmashri Ponnaluri
Primary Examiner
Art Unit 1627

September 27, 2001


PADMASHRI PONNALURI
PRIMARY EXAMINER



RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

FROM/ATTORNEY:

FIRM:

PAGES, INCLUDING COVERSHEET:

PHONE NUMBER:

TO EXAMINER: **P. Ponnaluri**

ART UNIT: **1627**

SERIAL NUMBER: 09/587,116

FAX/TELECOPIER NUMBER: (703) 308-4315

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